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Filed : May 31, 2002

### REMARKS

Claims 1, 7, 9, and 11 have been amended. Support for the amendments can be found in the specification as filed, for example, on page 8, lines 9-11. No new matter has been introduced by these amendments. The following addresses the substance of the Office Action.

#### Double patenting

Claims 1, 5 and 14 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 15 and 17 of copending Application No. 10/736,448. A terminal disclaimer may be used to overcome an obviousness-type double patenting rejection. Applicant will defer filing a terminal disclaimer until the rejected claims are otherwise indicated to be in condition for allowance.

#### Claim Rejections under 35 USC §112

The Examiner has rejected Claims 1-14 and 17-21 under 35 USC §112, second paragraph, as being indefinite. More specifically, Claim 1 was rejected for allegedly reciting an improper Markush group by including the word "comprising". Applicant respectfully disagrees. The proper Markush group of Claim 1 recites two types of compounds: alkylglycosides and alkyl-phosphorylcholine. Alkylglycosides are further defined as comprising within their structure unbranched, branched or cyclic C5-C12 alkyl chain (hence "alkyl"), and glycoside, selected from the group consisting of monosaccharides and disaccharides. Therefore, Applicant asserts that the Markush group in Claim 1 is proper. Claim 1 was further rejected because the phrase "providing said protein solubilized in a first detergent" is confusing. Applicant has amended Claim 1 to now recite "providing a protein from the family of G-protein-coupled receptors solubilized in a first detergent". Therefore, Claim 1 is now clear, and its rejection under 35 USC §112, second paragraph should be withdrawn.

Claims 7 and 18 have been rejected because "at least one conserved disulfide bridge" lacks antecedent basis in Claim 1. Applicant respectfully disagrees. Forming of at least one disulfide bridge is an additional limitation introduced in Claim 7 which depends on Claim 1, therefore it does not need an antecedent basis in Claim 1. However, the Applicant has amended Claim 7 by removing the term "conserved" to improve clarity of the claim.

Claim 9 has been rejected because the phrase "said protein is produced in form of inclusion bodies" is vague. Applicant respectfully disagrees. The term "inclusion bodies" is clearly defined in the specification as filed on page 2, lines 13-14 as "The aggregates of

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"inactive" protein are designated in English literature as inclusion bodies." However, to improve clarity of the claim, applicant has amended Claim 9 to now recite "said protein is produced as inclusion bodies". Therefore, Applicant asserts that Claim 9 is clear.

Claim 11 has been rejected because it was unclear if the first detergent is added before, after or both before and after the solubilization step. Applicant has amended Claim 11 to now recite "solubilizing said purified inclusion bodies by adding said first detergent". Therefore, Claim 11 is now clear.

For all of the above reasons, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 112, and allowance of the pending application.

#### **Claim rejections under 35 USC §102**

The Examiner has rejected Claims 1-3, 5, 6, 9-14 and 17-21 under 35 USC §102(a) as being anticipated by Kiefer et al. (December 1999) *Biochem. Soc. Trans.* 27:908. Applicant respectfully disagrees. 35 USC §102(a) states: "A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." The cited reference was published after the priority date of the present application of August 19, 1999. Therefore, the cited reference does not anticipate Claims 1-3, 5, 6, 9-14 and 17-21, and their rejection under 35 USC §102(a) should be withdrawn.

#### **Claim rejections under 35 USC §103**

The Examiner has rejected Claims 1-6, 8-14, 17 and 19-21 under 35 USC §103(a) as being unpatentable over Kiefer et al. (Biochem. 1996 35:16077) in view of Kiefer et al. (Biochem. Soc. Trans. (July 1999) A141) and Nekrasova et al. (Eur. J. Biochem. 1996 238:28). More specifically, the Examiner believes that it would have been obvious at the time the invention was made to employ lysophosphatidyl choline in the method taught by Kiefer et al. (1996). Kiefer et al (1996) teach refolding of an G-protein-coupled receptor protein by using two-detergent method; Kiefer et al. (July 1999) recommends using a milder detergent for the second step of the refolding method without disclosing any specific detergents; and Nekrasova et al. recommends using lysophosphatidyl choline for effective solubilization of membrane-bound proteins in non-denatured, active state, because it is milder than N-lauroyl sarcosine. Applicant respectfully disagrees.

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To establish a *prima facie* case of obviousness, the PTO must cite one or more references that provide some suggestion or motivation to modify the references to achieve the claimed invention, provide a reasonable expectation of success to achieve the claimed invention, and finally, the cited art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Here, the cited art either taken alone or in combination, fails to provide any of the required factors.

As will be established in the in re Katz Declaration signed by the inventors, which will be submitted shortly, Kiefer et al. Biochem. Soc. Trans. (July 1999) A141 reference is authored by the inventors. Therefore, this publication does not qualify as prior art under 102(a). Without the suggestion authored by the inventors in this abstract, a person with an ordinary skill in the art at the time the invention was made would not have been motivated to combine or modify the teaching of Kiefer et al. (Biochem. 1996 35:16077) and Nekrasova et al. (Eur. J. Biochem. 1996 238:28) to achieve the claimed invention. Therefore, 1-6, 8-14, 17 and 19-21 are not obvious under 35 USC §103(a) and their rejection should be withdrawn.

**Allowable subject matter**

Applicant wishes to thank the Examiner for indicating that Claims 7 and 18 are allowable if rewritten to overcome the rejections under 35 USC §112m second paragraph. Applicant has amended Claims 7 and 18 accordingly.

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### CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.


Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 21, 2004

By: \_\_\_\_\_

  
Marina D. Gordey  
Registration No. 52,950  
Agent of Record  
Customer No. 20,995  
(805) 547-5580

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